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No. 04-477

Supreme Court, U.S.
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In The Supreme Court of the United States

CHIRON CORPORATION,

Petitioner

v.

GENENTECH, INC.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The Federal Circuit has misinterpreted a key provision of the Patent Act, 35 U.S.C. § 112, to impose on patent applicants a requirement that has no support in the statutory text. It thereby disregards congressional intent, invalidates patents that fulfill the statutory requirements, and undermines the carefully crafted federal patent scheme. Moreover, the Federal Circuit has been inconsistent in its interpretation of its own judicially created requirement. The Federal Circuit's ruling is particularly pernicious because of that court's exclusive jurisdiction over patent appeals nationwide and the binding force of its opinions on examiners in the United States Patent and Trademark Office (PTO).

The United States has recognized the need for an authoritative interpretation of the requirements imposed by Section 112 to eliminate the conflict among panel opinions of the Federal Circuit on this important issue. *See* Brief of United States as *Amicus Curiae* Supp. Reh'g *En Banc*, No. 01-1230, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, at 4-5 (2002), available at http://www.uspto.gov/web/offices/com/sol/ambriefs/Enzo.pdf. It has emphasized that inventors, the public, and the PTO are in need of clear guidance on the correct interpretation of Section 112. *Id.* at 5. The case in which the United States expressed those views did not reach this Court because the Federal Circuit modified its ruling on other grounds, and the instant case now provides the Court with the opportunity to provide the critically needed guidance. If there is doubt concerning the Federal Circuit's jurisprudence on the issue, we respectfully suggest that the Court invite the views of the Solicitor General in this case in light of those earlier expressed views.

The Federal Circuit's treatment of the jury's general verdict also merits review because the ruling ignores settled doctrines of this Court and adds to the disarray among appellate courts on the issue.

A. The Priority Context Of This Case And The Outcome Determinative Nature Of The Separate Written Description Ruling Support Review

1. Respondent attempts to avoid the critical need for resolution of the conflict within the Federal Circuit by defending that court's erroneous interpretation of Section 112 only in cases that arise in a "priority" context. Br. in Opp. 1, 10-11. Priority claims arise when an invention claimed in a continuation-in-part patent application (here the 1995 application resulting in the '561 patent) benefits from the filing date of the initial patent application (here the 1984 application) because the specification in the initial application disclosed the claimed invention.

By its argument, respondent suggests that the text of Section 112 could be interpreted in priority cases differently than in non-priority cases, a result that is contrary to fundamental tenets of statutory construction. *See Leocal v. Ashcroft*, 125 S. Ct. 377, 384 n.8 (2004) (statutory provision must be interpreted consistently). Moreover, it illustrates the danger posed by the Federal Circuit's policy-based creation of non-statutory patent requirements which the Federal Circuit feels free to craft differently depending on the nature of the case rather than the text of the statute. *See* Br. in Opp. 13-15 (claiming textual support for Federal Circuit ruling without any textual analysis and relying instead on policy argument that patentee should be required to include separate evidence of possession in application).

The Federal Circuit went farther in this case than in *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir.), *cert. denied*, No. 04-476 (Nov. 29, 2004), and imposed its separate written description requirement to require a patent to describe the future (an impossible task, of course), or be invalidated when a later invention makes use of the patented invention in an improved manner (an outcome contrary to the incentive for invention created by Congress). Thus, the ruling below constitutes a particularly vivid example of the broad consequences of the Federal Circuit's erroneous reading of

Section 112 and presents an ideal case for this Court's review.

The fact that respondent succeeded in invalidating the patent only on the judicially created separate written description ground and not on the statutorily based enablement ground also makes this case a particularly good candidate for review. *See* Pet. App. 12a-13a (ruling that patent satisfied Section 112 enablement requirement). Unlike in *University of Rochester*, there can be no claim in this case that application of the separate written description requirement by the court of appeals had no effect. Indeed, the Federal Circuit's erroneous written description ruling was unquestionably outcome determinative. *Ibid.*

2. Respondent's reliance (Br. in Opp. 11-12) on the line of cases by the Federal Circuit imposing its separate written description requirement in priority cases serves only to illustrate the need for intervention by this Court. Unlike in other areas of law where the independence of the various federal courts of appeals permits divergent views on statutory interpretation to develop and then be resolved by this Court, there is no opportunity for such divergent views in patent law. No individual Federal Circuit panel may read the statute differently because it is bound by the contrary Federal Circuit precedent regardless of whether it agrees on the merits. *See* Fed. Cir. R. 35(a)(2). In *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991) (cited at Br. in Opp. 11, 12), the panel expressly cited the fact that "decisions of a three-judge panel of this court cannot overturn prior precedential decisions" when it applied the separate written description requirement in a priority case.

Furthermore, even bound by that restraint, members of the court have managed to question the validity of the circuit precedent. Respondent ignores this fact. In *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1327 (Fed. Cir.), *cert. denied*, 540 U.S. 982 (2003) (discussed at Br. in Opp. 12), Judge Bryson issued a concurring opinion expressly disavowing the argument that the written

description requirement can mean something different in the priority context, as respondent's reasoning now suggests. He pointed out that if that statutory analysis is raised, the real question is whether the entire line of priority cases "is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1," but he declined to take a position on the issue. *Id.* at 1328. Judge Rader also recognized in his concurring opinion that, "[a]lternatively, as indicated in Judge Bryson's concurring opinion, the problem in this area of the law may lie in the line of cases stemming from the *Ruschig* [priority] case." *Id.* at 1327.

Our petition demonstrates that the Federal Circuit relied on a fundamentally flawed construction of Section 112 to impose its separate written description requirement. Pet. 18-20. Respondent provides absolutely no textual analysis to identify any language in the statute that could support such a requirement.[1]

B. Respondent Misconstrues The Record And The Disincentive For Inventions That May Later Be Improved

1. Respondent misconstrues the record of this case to argue that petitioner attempted to misuse its patent application to stake a claim to the future. Br. in Opp. 3, 15. But petitioner makes no claim to a patent on respondent's Herceptin nor to the improvement to petitioner's invention that occurred when the "animal-derived binding sites" that petitioner had invented were "humanized" by "surrounding" them "with human DNA" to lessen the adverse reaction in a human body. Pet. App. 64a.

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[1] Respondent's quotation (Br. in Opp. 12 n.8) from *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), is unavailing because that dicta does not analyze whether the written description requirement is separate from enablement. Moreover, as noted in our petition (at 18), *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001), describes Section 112 as requiring only a description that meets the statutory enablement standard.

What petitioner invented was a monoclonal antibody that binds to the HER2 antigen. It has ownership rights to that invention for the limited life of the patent, apart from rights that others have to humanization technology, or rights that respondent has to Herceptin.

Respondent is wrong (Br. in Opp. 3, 5, 16) that petitioner's 1984 application "described" or "disclosed" only "murine antibodies" that bind to HER2. The district court, in construing the patent claims, found that "[a]lthough the [1984] application discusses primarily murine monoclonal antibodies," the application's written description of the invention "expressly contemplate[s] other embodiments of the claimed invention" and makes "clear * * * that the importance of the invention is not its murine hybridoma-derived structure, but its ability to selectively bind to human breast cancer cells, and its usefulness as an effective therapeutic against cancer." C.A. J.A. 86, 92, 93-94.

The district court found that the humanized antibodies used by respondent are, and would have been understood in 1984 to be, monoclonal antibodies as that term was used in petitioner's 1984 application. Pet. 5 n.2; *see also* Pet. App. 3a-4a (court of appeals concluding that murine, chimeric, and humanized antibodies are all "monoclonal antibodies" produced by "various methods").[2]

2. Under the Federal Circuit's view, it is the existence of improved inventions (chimeric and humanized monoclonal antibodies that bind to HER2) that fall within the explicit scope of the patent's claims which

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[2] Respondent's repeated suggestions (Br. in Opp. 3, 6, 7, 16, 18) that the HER2 antigen was somehow unknown to petitioner and unidentified by the 1984 application are baseless. An antibody binds to a specific antigen. Pet. App. 3a. At the time of petitioner's initial patent application in 1984 for the monoclonal antibody that binds to HER2, an antigen like HER2 was commonly defined by the antibody which binds to it. *See, e.g.*, C.A. J.A. 1475. There is no dispute that the monoclonal antibody that petitioner identified in its 1984 application binds to HER2.

invalidate the patent based on inadequacy of its written description of the invention (monoclonal antibodies that bind to HER2). Thus, the Federal Circuit imposes the impossible burden of supplying a separate written description that must catalogue individual manifestations or embodiments of a patent, including in this instance later-appearing humanized antibodies.

To illustrate, consider a hammer. One inventor develops a novel design for a hammer head and files a patent claiming a hammer with that type of head as his invention. The patent has examples of hammers with the new head design where the handle is made of wood, but the claims do not specify any type of handle material. A second inventor later develops a new composite material to use for the handle because it dampens vibration. The second inventor then markets hammers with the new head design and the new composite material handles without obtaining a license from the first inventor to use the head design. Under the Federal Circuit's holding, the first patent holder loses an infringement action and, more remarkably, has his hammer patent invalidated for failing to describe the later-developed handle material in the original patent application, even though that material did not exist at the time of the application. Although the initial patent does not give the patentee any right to the new improved handle material, there is no rationale for taking from the first patentee his right to license his hammer with the new head design. It is inconceivable that Congress intended such a nonsensical result.

Judge Learned Hand's observation that an invention's future interaction with new technologies need not be completely foreseen in order for a patent to protect it remains persuasive. *B.G. Corp. v. Walter Kiddie & Co.*, 79 F.2d 20, 22 (2d Cir. 1935).

C. The Purported Alternative Grounds For Affirmance Are Without Merit

1. Petitioner's continuation-in-part application that ultimately issued as the '561 patent at issue here included

many pages disclosing additional embodiments of its invention and seeking other quite different claims that were eventually rejected. The '561 patent did not, however, inject any new matter prohibited by 35 U.S.C. § 132(a) with regard to the invention at issue for which the PTO granted the patent and gave priority back to the 1984 application. Pet. 5.

It is curious for respondent now to raise new matter under Section 132 as its first alternative ground for affirmance (Br. in Opp. 4, 19-20), because respondent stipulated in the trial court that if the 1984 patent application complied with the first paragraph of Section 112 the patent was valid. Pet. App. 7a; C.A. J.A. 1, 3457. Respondent did not make any new matter challenge, apparently recognizing that Section 132 applies to amendments to pending applications, not to the priority of subsequent applications to earlier ones.[3]

2. Respondent's second purported alternative ground for affirmance is similarly unavailing. The court of appeals correctly rejected that enablement argument. Judge Bryson reached a contrary result in his concurring opinion only by disregarding a long and undisputed line of precedent that has garnered no disagreement in the Circuit. *See* Pet. 26-27. In addition, even if respondent were correct on enablement (which it is not), such a ruling could not serve as an alternative ground for affirmance if the separate written description ruling were reversed because the jury verdict could have been based on the legally unsound written description ground. *See infra*, pp. 9-10.

3. Respondent's attempt to avoid this Court's review (Br. in Opp. 21) by invoking as a third alternative ground

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[3] Respondent's suggestion (Br. in Opp. 16-17) that the separate written description requirement is tied to the Section 132 new matter prohibition also is in tension with its claim elsewhere that the judicially created requirement is imposed to obtain proof of possession (Br. in Opp. 3, 19). The Federal Circuit also has adopted divergent views of its judicially created requirement on different occasions. *See* Pet. 15-16; Br. of United States as *Amicus Curiae* in *Enzo*, *supra*, at 4-5, 9.

for affirmance a claim construction argument is disingenuous inasmuch as it did not challenge the district court's claim construction in the Federal Circuit "in the first instance," and raised it only conditionally as a cross-appeal in the event the jury verdict was reversed. Pet. App. 11a. Respondent itself urged the court of appeals not to reach that cross-appeal unless respondent lost on all other grounds. C.A. Resp. Br. 68.

Further, any possibility that the court of appeals would reverse the district court's claim construction and construe the claim contrary to its explicit definition is extraordinarily remote. *See* Pet. App. 18a, 19a (court noting that respondent could prevail only if the court were willing to construe the term monoclonal antibody "contrary to the explicit definition of the '561 patent").

D. The General Verdict Ruling Conflicts With This Court's Case Law And Further Exacerbates The Disarray In The Lower Courts

1. Respondent's attempt (Br. in Opp. 4, 22) to dismiss the need for review of the lower court conflict on the general verdict issue as "fully answered" by the Court's denial of review in *Union Pacific Railroad Co. v. Barber*, No. 04-47 (Oct. 12, 2004), completely disregards the substantial questions in that case regarding whether the petitioner there had raised the issue in the lower courts. Resp. Br. in Opp. *Union Pacific Railroad Co. v. Barber*, No. 04-47, at 25-27. There is no comparable question regarding whether the issue was properly raised below in the instant case because it clearly was, *see* Pet'r C.A. Br. 52; Pet'r C.A. Reply Br. 23-24; Pet'r Pet. for Reh'g 3 n.1, and respondent does not claim otherwise.

Also, the instant case arises from a federal court and therefore does not involve the issue raised by respondent in *Union Pacific*, Resp. Br. in Opp. in *Union Pacific Railroad* at 25-26 n.15, regarding the ability of a State to adopt different rules for its own courts. By contrast, denial of review in this case will mean that the federal courts of appeals will continue to apply different rules.

2. Respondent's contention (Br. in Opp. 3-4) that "[t]he jury agreed" that respondent had proven by clear and convincing evidence that petitioner's 1984 application "did not satisfy the written description requirement of Section 112" is without any support in the record. The record is equally consistent with the jury having rendered its verdict based solely on the failure of the patent application to meet the enablement requirement – a conclusion that the Federal Circuit determined was incorrect "as a matter of law."

When one of the grounds for a jury's verdict is invalidated on appeal in that manner, this Court's precedent provides that "a new trial is required" because there is "no way to know that the invalid claim * * * was not the sole basis for the verdict." *United New York & New Jersey Sandy Hook Pilots Ass'n v. Halecki*, 358 U.S. 613, 619 (1959); *see also Maryland v. Baldwin*, 112 U.S. 490, 493 (1884). Respondent agrees (Br. in Opp. 22) that *Baldwin* and its progeny mean that "a general jury verdict, which may have rested on a theory of liability found erroneous on appeal, cannot stand."

Respondent's suggestion (Br. in Opp. 23) that the courts of appeals are merely relying on a harmless error exception is but an element of the split in the lower courts, because some courts of appeals have understood *Baldwin* and its progeny to preclude harmless error analysis. *See Farrell v. Klein Tools, Inc.*, 866 F.2d 1294, 1300 (10th Cir. 1989) ("no room for harmless error analysis"); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 136 n.4 (3d Cir. 1999) (Cowen, J., dissenting) ("Most of the circuits * * * have strictly adhered to the general rule announced in *Baldwin*" and have not utilized "a harmless error analysis."), *cert. denied*, 528 U.S. 1074 (2000). In any event, there is no indication that the Federal Circuit relied on harmless error in this case because it recited a deferential standard for reviewing a jury's factual findings, Pet. App. 8a, and stated that "the jury *may have found*" that the 1984 application did not meet the written description requirement. Pet. App. 13a (emphasis added) Contrary to

respondent's novel suggestion (Br. in Opp. 4, 23), the Federal Circuit did not hold that respondent was entitled to a judgment as a matter of law on the separate written description requirement, regardless of the jury's verdict. Indeed, respondent never sought such a declaration, explaining to the Federal Circuit that compliance with the written description requirement was a "question of fact for the jury," whose finding was entitled to "deference." Resp. C.A. Br. 26-27. The district court, moreover, rejected respondent's pre-trial motion for summary judgment on the written description issue, finding the question involved disputes of material fact for a jury to resolve. C.A. J.A. 909-919.

CONCLUSION

For the reasons set forth above and in the petition for a writ of *certiorari*, the petition should be granted.

Respectfully submitted,

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